

Charles M. Auer. Director

Chemical Control Division (7405)

Environmental Protection Agency

Office of Pesticides and Toxic Substances

BIPHENYL WORK GROUP

1850 M Street, N.W., Sulte 700 Washington, D.C. 20036 (202) 721-4162 - (202) 296-8120fax

August 6, 1999

42187

92187 CL-181

Ela-181

lp

40990000121

Re: ECA Proposal for HAPs Testing of Biphenyl

Dear Mr. Auer:

Room E513C 401 M Street, S.W. Washington, D.C. 20460

The Biphenyl Work Group (BWG) appreciates the careful review you and your staff gave to our October 7, 1997 proposed test program for biphenyl. That program, developed with the assistance of Dr. Melvin E. Andersen, called for a 90-day inhalation study, pharmacokinetic studies, and development of a physiologically-based pharmacokinetic (PBPK) model. BWG remains committed to developing a program that makes maximal use of existing animal data through PBPK modeling. Such an approach not only eliminates unnecessary costs, but also responds to animal welfare concerns by limiting the need for additional *in vivo* testing.

The BWG and Dr. Andersen have carefully reviewed EPA's comments. We understand the need to supplement our prior filing with additional testing elements in some areas; but, in other areas, substantial scientific questions raised by your comments cause us to want to sit down with your staff to explore thoroughly exactly what EPA seeks and the best means of achieving that aim. These questions need to be answered before we can determine whether it would be useful to develop, and, if so, the scope of, any further ECA proposal.

We therefore request a meeting with you and your staff to clarify the Agency's position. We would bring Dr. Andersen to such a meeting. Please ask Rich Leukroth to call me with possible meeting dates as soon as possible.

John F. Murray, CAE Executive Director

cc:

Richard W. Leukroth, Jr. HAPs Project Manager (7405)

OPTS Docket 42187A &B (7407)

BWG Group

Dr. Andersen

L. Mark Wine

Counsel to BWG

